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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,184	12/19/2001	Chad Cori Huval	1932.1064-033	8481

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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/025,184	HUVAL ET AL.	
	Examiner	Art Unit	
	LEONARD M. WILLIAMS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-3 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-3 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/11/2008 has been entered.

Response to Arguments

No amendments have been made to the claims. New claims 14 and 15 have been added. Claims 2-3 and 8-15 are currently pending.

Applicant's arguments filed 02/11/2008 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant's argue that as Keim's polymers (which are identical to applicant's presently claimed polymers) are water-soluble they would not lead one to utilize the said polymers in a method making tablets. There are no clear reasons why such an assertion is supported. Indeed it is common to incorporate water-soluble and water-insoluble components in tablet formulation based upon the active pharmaceutical ingredients used. Further McTaggert et al. describes tablet and solution formulations for similar polymers with no problems as to the polymers water solubility or insolubility. For the reasons listed above and for the reasons of record the 103(a) rejection has been modified to include the newly added claims and the modified 103(a) rejection is maintained. No new references have been used in the rejection.

The modified rejection is detailed below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-3 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keim et al. (US Patent No. 3700623) in view of McTaggart et al. (US Patent No. 5462730).

Keim et al. teach, in col. 1 lines 20-55, water-soluble resinous reaction products of a polymer of a diallylamine and an epihalohydrin such as epichlorohydrin. The resins are fast curing, water-soluble, and efficient. In example 5, 5g of diallyl amine monomer

is reacted with 1g of epichlorohydrin cross-linking agent giving a 20% by weight amount of cross-linking agent. In example 6 the polymer to cross-linking agent percentage is 15.9%. In column 2 lines 63-70, Keim et al. teaches that the polymers can be homopolymers or copolymers and can exists as the salts or freebase of the final amines. Keim et al. teach, in col. 3 lines 50-70, that the resinous products are soluble in water and the pH of the solutions can be adjusted to 6 or 5 by addition of hydrochloric, sulfuric, phosphoric, and acetic acids.

Keim et al. does not explicitly teach the resin to be used in pharmaceutical compositions.

McTaggart et al. teaches, in col. 1 line 10- col. 2 line 40, poly(allylamine)polymeric materials (that can be cross-linked) useful in the formulation of pharmaceutical agents for sequestering bile acid and thus having utility in treating a variety of disorders including hypercholesterolemia, etc...In col. 9 line 5 to col. 10 line 28, McTaggart et al. teach that the polymeric allylammonium compositions can be formulated in suspensions and as tablets for oral administration. Further the polymeric materials can be prepared as solids and as aqueous and non-solutions based upon the properties of the polymers.

One of ordinary skill in the art at the time the invention was made would recognize that Keim et al's. homopolymer (capable of being neutralized by pharmaceutically acceptable acids) could be formulated into pharmaceutically forms (such as tablets) for oral administration as McTaggert demonstrates that similar polyallylamine polymers can be formulated as such. Further McTaggart et al.

Demostrate that polyallylamine polymers of this type have utility as bile sequestering agents. As the homopolymers Keim et al. detail are exactly the polymers currently claimed, the properties the applicant's have discovered are inherently present in Keim et al's. homopolymers. Thus the homopolymers currently claimed were known and similar polymers have already been formulated into pharmaceutical forms for use as bile acid sequestrants. The addition of new claims 14 and 15 wherein the polydiallylamine homopolymer is water-insoluble does not overcome the fact that the polydiallylamine homopolymers as claimed are still identical to those described in Keim et al.

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEONARD M. WILLIAMS whose telephone number is (571)272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. M. W./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617